Registration Decision RD2017-08

Deltamethrin

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Registration Decision Statement[1] for Deltamethrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Deltamethrin Technical Insecticide and DeltaGard 20EW, containing the technical grade active ingredient deltamethrin, to control adult mosquitoes in residential and recreational areas.

This decision is consistent with the Proposed Registration Decision PRD2017-05, *Deltamethrin,* which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2017-05, *Deltamethrin*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[2] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

[2] As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Comments and Responses

In response to the consultation document Proposed Registration Decision PRD2017-05, *Deltamethrin*, comments were received from stakeholders, including non-governmental organizations and the public. A number of comments expressed similar concerns and were, therefore, consolidated and summarized, with responses provided below.

1.0 Comment on spraying in rural areas

A question was raised as to whether the product can be sprayed in rural areas.

PMRA Response

In rural areas, DeltaGard 20EW may be applied in non-crop areas adjacent to cropland. It may also be applied in residential, industrial, urban/municipal and recreational areas.

2.0 Comment on effectiveness

A comment was received pointing out that fogging is ineffective in controlling mosquito populations which carry diseases.

PMRA Response

As stated in the Proposed Registration Decision PRD2017-05, *Deltamethrin*, efficacy studies showed that DeltaGard 20EW provided 94-100% control of adult mosquitoes. Furthermore, fogging provides rapid control of adult mosquitoes according to the American Mosquito Control Association, and is recommended by the World Health Organization.

3.0 Comment on resistance in mosquito populations

A comment was received with the suggestion to cease the registration of deltamethrin products due to resistance in mosquito populations.

PMRA Response

Trials demonstrated 94-100% control of field populations of mosquitoes in seven locations including Manitoba, as discussed in the Proposed Registration Decision PRD2017-05, *Deltamethrin*. As with most pesticides, there is a potential for mosquitoes to develop resistance to deltamethrin. To mitigate the risk of resistance developing, resistance management recommendations are located on the DeltaGard 20EW label. These include recommendations to rotate deltamethrin with other modes of action and the use of an Integrated Pest Management (IPM) program.

4.0 Comment on alternatives

A comment was received indicating that emphasis should be placed on alternative control strategies (for example, reducing standing water, citizen education, larval control).

PMRA Response

Statements recommending the use of Integrated Pest Management (IPM) strategies are located on the DeltaGard 20EW label. DeltaGard 20EW provides an additional product for control of mosquitoes which can be used in conjunction with other mosquito control strategies. Methods of mosquito control which are recommended by Health Canada as part of a mosquito control program (https://www.canada.ca/en/health-canada/services/pest-control-tips/mosquitoes.html) include use of a registered larvicide and non-chemical control methods (e.g., draining standing bodies of water).

5.0 Comments on decamethrin

Comments were received relating to the metabolite decamethrin.

PMRA Response

Decamethrin is not a metabolite; it is an old name/synonym of deltamethrin.

6.0 Comments on animal populations

Comments were received relating to harm to animal populations, and toxicity for bees, beneficial insects, aquatic organisms.

PMRA Response

Deltamethrin, when used for control of adult mosquitoes, is not expected to cause harm to animal populations, bees, beneficial insects and aquatic life. Deltamethrin, when used as DeltaGard 20EW, will be applied by fogging using ultra-low volume (ULV) sprayers. This means that the droplets of pesticide that are released during treatment are very small and will not fall or deposit on soil and vegetation, or into water, like larger droplets. These small droplets of pesticide will remain suspended in the air until they evaporate. The pesticide in the droplets is also expected to breakdown in air. As a result, the amount of pesticide deposited on land, vegetation and water is expected to be minimal. Harm to beneficial insects and other animals is not expected because any remaining concentrations of deltamethrin in the environment will not be high enough to cause toxicity to these organisms. Additionally, fogging treatments such as this are typically carried out at night or in early morning when adult mosquitoes are most active, and other non-target organisms are normally less active. This also reduces the potential for these organisms to be exposed to deltamethrin through fogging.

7.0 Comments on persistence

Comments were received relating to persistence in outdoor and indoor environments.

PMRA Response

Deltamethrin is expected to degrade rapidly in the air, as it is susceptible to photochemical oxidative reactions (half-life is estimated to be 16 hours). Based on scientific studies conducted in the laboratory and outside under field conditions, deltamethrin can be broken down by microbes in the soil and water, and is considered to be non-persistent to moderately persistent in both of these environments. When applied as fine droplets/fogging, deltamethrin is expected to dissipate quickly through volatilization and atmospheric reactions. Thus, deposit into aquatic and

terrestrial systems from this type of application is greatly reduced and exposure to the environment is expected to be minimal.

8.0 Comments regarding the respirator requirement

Comments were received that disagreed with the requirement for a respirator as part of the personal protective equipment (PPE) during mixing, loading, and application of DeltaGard 20EW when using a vehicle-mounted with an Ultra Low Volume (ULV) sprayer. The United States Environmental Protection Agency (USEPA) human health risk assessment for deltamethrin was also referenced, which does not identify a requirement for a respirator.

PMRA Response

The DeltaGard 20EW label submitted by the applicant stated PPE for all mixers, loaders, and applicators and included a respirator with a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister for pesticides, without specifying for which equipment it was required.

Following clarification by the applicant, the risk assessment has been revised such that the PPE reflects only a single layer and chemical-resistant gloves. The resulting margin of exposure (MOE) for inhalation is much higher than the target MOE of 300. As such, inhalation risks to workers mixing, loading, and applying DeltaGard 20EW, without the use of a respirator, are not of concern (Table 1). Therefore, PMRA supports the removal of the respirator from the DeltaGard 20EW label.

Table 1 Mixer/loader/applicator dermal and inhalation exposures and risk estimates.

Exposure scenario	Dermal unit exposure (µg/kg a.i. handled)[1]	Inhalation unit exposure (µg/kg a.i. handled)[1]	Max. Area Treated per day[2] (ha/d)	Amount ai handled per day (kg ai/day)	Daily dermal exposure (mg/kg bw/day)[3]	Daily inhalation exposure (mg/kg bw/day)[3]	Dermal MOE¶	Inhalation MOE¶
PPE: Long-sleeved shirt, long pants, chemical-resistant gloves, and shoes plus socks								
Airblast Mixer/ Loader/ Applicator (for ground-based, truck-mounted ULV equipment)	3820.44	**10.68**	1200	1.8	0.08596	**0.000240**	11633	**4161**

In comparison to Table 3.4.2.1-1 in the Proposed Registration Decision PRD2017-05, *Deltamethrin*, **the revised values are bolded**.

[1] Mixer/loader unit exposures from PHED database; applicator unit exposures from AHETF database.

[2] ATPD for the application equipment is taken from PMRA default ATPD Tables (airblast, 1200 ha/d), assumed to be undiluted spray volume, as a conservatism.

Amount ai handled per day (kg ai/d) = Maximum area treated per day (ha/d) × 0.001kg/g × application rate (1.5g deltamethrin/ha)

[3] Daily exposure = (Unit exposure × Amount ai handled/day) / (80 kg bw × 1000 µg/mg);

¶ Margin of Exposure (MOE) = Toxicological endpoint / Exposure; dermal endpoint is a $NOAEL_{dermal}$ = 1000 mg/kg bw/day, target MOE = 1000; Inhalation endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

9.0 Comment regarding a timeframe to enter treated sites

A comment was received that included a request for an appropriate time to enter treated sites, especially for individuals who may have sensitivities to certain substances.

PMRA Response

The current risk assessments do not require a restricted entry interval (REI) as there are no unacceptable risks (dermal, inhalation and oral) to individuals entering residential treated sites during or after treatment(s) when the product is used in accordance to the label.

While no special precautions are necessary or required for bystanders, individuals who have concerns could take reasonable precautions to avoid further exposure during a spray program in the same way they would avoid other airborne materials during days when air quality advisories are issued. For example, they can also reduce exposure by staying indoors, closing all windows and doors and shutting off outdoor vents (for example, air exchangers and heat recovery ventilators) during the spray period if spraying is taking place in their area, although this may not be required by the local health officials.

10.0 Comments relating to the toxicology assessment for human health risk evaluation

Several comments were received from the public in which concerns were expressed relating to use of DeltaGard 20EW and the potential for adverse health effects in humans, including sensitive populations, such as the elderly, pregnant women, and babies. Some commenters indicated that information within Proposed Registration Decision PRD2017-05, *Deltamethrin*, was limited with respect to how these populations were considered in the risk assessment. Comments regarding the potential of deltamethrin to cause neurotoxicity, chromosome damage, cancer, and effects on the endocrine system were received. In addition, comments were received regarding the potential for deltamethrin to cause sensitization and asthma, especially in chemically sensitive individuals. Finally, there was a comment regarding whether consideration was given in the risk assessment to multiple applications over the course of the spring and/or summer months with DeltaGard 20EW.

PMRA Response

A comprehensive toxicology database is available for deltamethrin, and detailed assessment of the toxicological data has been carried out by PMRA, allowing for thorough characterization of the health effects associated with deltamethrin. The toxicology reference values used in the risk assessments are protective of these effects.

In evaluating the safety of a pesticide, PMRA considers two key factors: the levels where no health effects (hazards) are expected to occur and the levels to which people may be exposed. Registrant-supplied data such as laboratory animal toxicology studies, as well as information from the published scientific literature, are critically assessed for the potential of a pesticide to cause various health effects. These include cancer and effects on different populations (such as the young), different organ systems (such as the nervous and immune systems) and varying durations of exposure (such as single and lifetime exposures). Potentially sensitive human subpopulations (for example, children and nursing mothers) as well as sex and gender are taken

into account in the risk assessment. The risk assessment ensures that the level of exposure to humans is well below the lowest dose at which effects occur in laboratory animal testing. Only uses which meet the PMRA's level of acceptable risk are considered for registration.

A detailed description of how the PMRA determines acceptable risk is available in the Science Policy Note SPN2000-01, *A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*.

A detailed review of the toxicology database for deltamethrin was conducted and is summarized in the Proposed Re-evaluation Decision PRVD2015-07, *Deltamethrin*. Further information on the end-use product, DeltaGard 20EW, is summarized in the Proposed Registration Decision PRD2017-05, *Deltamethrin*. Relevant information to the comments received is included below. For a full discussion of the risk assessment and toxicology reference doses selected for deltamethrin, please see Proposed Re-evaluation Decision PRVD2015-07, *Deltamethrin*.

A complete and comprehensive toxicology database is available for deltamethrin. The toxicology studies assessed a variety of endpoints and mammalian species, allowing for a thorough characterization of the potential hazards associated with this active ingredient following varying durations of exposure. The database included acute, short- and long-term dosing studies. In addition to studies assessing the potential to cause cancer, the database included studies which examined effects on various organ systems including the nervous and endocrine systems.

- **Relating to neurotoxic potential:** The toxicology database contained specific studies designed to assess neurotoxicity following single exposures as well as repeat exposures. Effects on the developing nervous system were also assessed for deltamethrin. The nervous system was the primary target of toxicity for deltamethrin. However, neurotoxicity did not increase with increasing duration of oral exposure to deltamethrin. The toxicology reference values used in the risk assessment are protective of these effects.

- **Relating to chromosome effects and carcinogenicity:** The active ingredient deltamethrin was not genotoxic in a battery of acceptable in vitro and in vivo studies, with no evidence of chromosome damage in mammalian cells. In addition, there was no evidence of carcinogenicity in mice or rats following dietary exposure to deltamethrin over a lifetime.

- **Relating to sensitization:** There was no evidence that the active ingredient deltamethrin produced a skin sensitization response in laboratory animals. Temporary local skin effects, such as itching, tingling or burning sensations of the skin, have been reported in some individuals, following acute dermal exposure to some pyrethroid pesticides, including deltamethrin. This reaction is not to be confused with skin sensitization. These local skin effects do not reflect an immune response and resolve shortly after exposure is discontinued. There was no evidence of overt toxicity to the immune system in the deltamethrin toxicology database.

An allergic skin reaction following dermal exposure to the end-use-product DeltaGard 20EW was observed in laboratory animals; however, the doses required to generate this response were many magnitudes of order higher than the exposure levels expected with the use pattern of DeltaGard 20EW. Therefore, although no specific precautions are necessary for individuals (for example, bystanders), those individuals who either have known sensitivities to certain chemicals or would like to take additional steps to avoid further exposure during a spray program can do so in the same way they would avoid other airborne materials during days when air quality advisories are issued. For example, they could reduce exposure by staying indoors, closing all windows and doors and shutting off outdoor vents (for example, air exchangers and heat recovery ventilators) during the spray period if spraying is taking place in their area, although this may not be required by the local health officials.

- **Relating to asthma:** With regards to the potential for respiratory effects, an integrative assessment was conducted by the USEPA in 2009 to determine the relationship between pyrethrins/pyrethroid exposure and asthma and allergies. This review incorporated animal and human data. The results of this assessment did not identify a clear association between pyrethrins/pyrethroid exposure and asthma and allergies. Therefore (and as mentioned above), while this may not be required by the local health officials, individuals can take additional steps to avoid further exposure during a spray program in the same way they would avoid other airborne materials during days when air quality advisories are issued.

- **Relating to effects on the endocrine system:** The examination of multigeneration reproductive toxicity assays and chronic toxicity/carcinogenicity assays helps to inform the assessment of potential endocrine-related toxicity. These studies have the potential to reveal numerous endpoints that may be directly or indirectly related effects on the endocrine system. There is some indication of toxicity to the male reproductive system with deltamethrin in animal studies; however, the toxicology reference values used in the risk assessment are protective of endocrine-related effects.

- **Relating to sensitive subpopulations:** Requirements for registration include studies to address the sensitivities of vulnerable populations. These include studies assessing effects on the maternal animal and fetus during pregnancy and on the young animal after birth through to adulthood. The PMRA conducts specific risk assessment for sensitive groups including children and pregnant women, taking physiological characteristics into account. The unique exposures of children are considered in a PMRA evaluation and could include minute exposure to pesticide residues in breast milk, formula or fruits and vegetables, exposure through skin contact with treated surfaces while crawling and playing, and exposure through incidental ingestion from behaviours such as hand-to-mouth transfer activity patterns for young children.

  The Proposed Re-evaluation Decision PRVD2015-07, *Deltamethrin*, presents the evidence for sensitivities for various subpopulations. The PRVD acknowledges that the pregnant animal may be a sensitive subpopulation. It is also acknowledged that, because of their immature detoxification mechanisms, the young are also considered a sensitive subpopulation. The toxicology reference values used in a risk assessment are protective

of the effects in the identified sensitive subpopulations.

Finally, it is important to note that, of the standard 100-fold uncertainty factor used in risk assessment, 10-fold accounts for natural variability within the human population. This factor accounts for variables such as age, for example the elderly, sex/gender differences, and variability in individual health status.

References

A. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

USEPA. 2009. A Review of the Relationship between Pyrethrins, Pyrethroid Exposure and Asthma and Allergies. United States Environmental Protection Agency Office of Pesticide Programs. https://www.epa.gov/sites/production/files/2015-08/documents/pyrethrins-pyrethroids-asthma-allergy-9-18-09.pdf